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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,418	09/05/2003	David J. Parins	1001.1675101	7562
28075 7590 01/16/2009 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,418

Applicant(s)

PARINS, DAVID J.

Examiner

JEFFREY G. HOEKSTRA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,12-14,21,22,30,31,38,39 and 44-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11,15-20,23-29,32-37 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/08/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 10/08/2008, amended claim(s) 1 is/are acknowledged. The current rejections of the claim(s) 1, 6-11, 15-20, 23-29, 32-37, and 40-43 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 10/08/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 10, 15, 16, 17, 19, 23, 24, 25, 27, 28, 32, 33, 34, 36, 40, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Johansen et al. (US 7,303,533 B2, hereinafter Johansen).

5. For claims 10, 19, 28, and 36, Johansen discloses and shows an intracorporeal device (10 and/or 20) comprising a guidewire (10 and/or 20), comprising *inter alia*:

- an elongate shaft (column 2 lines 48-52) inherently having a proximal end and inherently having an opposing distal end;
- a helically wound coil (20) (as best seen in Figure 2) (column 3 lines 27-67) having a plurality of windings (24) (as best seen in Figure 2) (column 3 lines 27-67), inherently having an outer perimeter (the outer perimeter of helically wound coil 20 as best seen in Figure 2), and inherently forming a coil length (the coil length of helically wound coil 20 as best seen in Figure 2), said coil length disposed about a portion of the distal end of the elongate shaft (column 2 lines 48-52); and
- a plurality of joining elements (22) (as best seen in Figure 2) (column 3 lines 27-67) disposed on only a portion of the outer perimeter (as best seen in Figure 2) (as best seen in Figure 2) (column 3 lines 27-67) and along the coil length (as best seen in Figure 2) (column 3 lines 27-67), wherein each joining element only couples two or more coil windings (column 3 lines 27-67), and wherein each joining element is a discrete element (as best seen in Figure 2) (column 3 lines 27-67).

6. For claims 15, 23, 32, and 40, Johansen discloses and shows the guidewire, wherein the joining elements form a uniform pattern of joining elements along the coil length (as best seen in Figure 2) (column 3 lines 27-67).

7. For claims 16, 24, 33, and 41, Johansen discloses and shows the guidewire, wherein each joining element couples 3 to 10 coil windings (as best seen in Figure 2) (column 3 lines 27-67).
8. For claims 17, 25, 34, and 42, Johansen discloses and shows the guidewire, wherein each joining element is a discrete element aligned orthogonal to the windings in a radial direction (as best seen in Figure 2) (column 3 lines 27-67).
9. For claim 27, Johansen discloses and shows the guidewire, wherein each joining element is disposed on less than 1/10 of the outer perimeter of each winding (as best seen in Figure 2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 6-9, 11, 18, 20, 26, 29, 35, 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen.
12. For claims 1, 6-9, 11, 18, 20, 26, 29, 35, 37, and 43 Johansen discloses and shows the guidewire as set forth and cited above, including the claim limitations of claims 6-8 (see paragraphs 6-8 above), except for expressly disclosing (a) the plurality of joining elements comprising at least ten joining elements disposed along the coil

length and (b) each joining element has a width in the range of 0.1 to 0.5 mm and a length in the range of 0.1 to 1.5 mm.

13. As evidenced by Applicant “the number and size of the joining elements can be varied to obtain the desired characteristics”. The Specification at at least pages 7-8 reads as follows:

14. *“A plurality of joining elements 120 can be disposed along the coil length L. The joining elements couple a plurality of coil windings 105 together. Each joining element 105 may join from 2, 3, 4, 5, 6, 7, 8, 9, or 10 or more coil windings 105 together. There may be 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40 or more joining elements 120 disposed in a uniform or non-uniform pattern along the coil length. In at least some embodiments, the joining elements 120 may only function to join coil windings 105 together. For example, in at least some embodiments, the coil joining element or elements 120 join a plurality of coil windings 105 together, but do not act to join any other structure within the device 100. In such embodiments, the coil joining element or elements 120 act only to join coil windings 105 together, and do not join any other structure to the coil. For example, in some such embodiments, the joining elements 120 do not join the coil 110 to the shaft or core 130.*

15. *“The joining elements 120, by interconnecting a series of coil windings, can provide enhanced torque transmission along the coil length L and/or enhanced push-ability while still providing flexibility that a coil 110 offers. The degree of enhanced torque transmission and/or push-ability is dependent at least in part on the number of joining elements along the length of the coil, and the size of each joining element (i.e.*

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the number of coil windings joined by each joining element). Those of skill in the art, and others will recognize that as a general proposition, that greater enhanced torque transmission and/or push-ability can be achieved by using a greater the number of joining elements along a coil length, and/or by increasing the number of coil windings 105 joined by each joining element 120. The number and size of the joining elements 120 can be varied to obtain the desired characteristics.

16. *“In some embodiments, the joining elements 120 may have a length in the range of about 0.1 to about 1.5 mm and a width in the range of about 0.1 to about 0.5 mm. The joining elements 120 can be discrete elements aligned orthogonal to the coil windings 105 as illustrated in Fig. 1. The joining elements 120 may be formed of a material the same as or different from the coil 110. The coil windings 105 define an outer perimeter 150. The joining elements 120 can be disposed about the outer perimeter 150 such that only a portion of the outer perimeter 150 is covered by joining elements 120. In some embodiments, each joining element 120 may be disposed on less than 1/10 of the total outer perimeter 150 of each winding 105.”*

17. Johansen discloses the claimed invention but does not disclose expressly the number and size of the joining elements as claimed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Johansen with the number and size of the joining elements as claimed, because Applicant has not disclosed that the number and size of the joining elements as claimed provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's

invention to perform equally well with configuration of the joining elements as taught by Johansen, because it provides for configuring the degree of stiffness, flexibility, and torqueability of the guidewire by altering the number of welds (i.e. joining elements) (column 3 lines 55-58) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Johansen. Therefore, it would have been an obvious matter of design choice to modify Johansen to obtain the invention as specified in the claim(s).

Response to Arguments

18. Applicant's arguments with respect to claims 1, 6-11, 15-20, 23-29, 32-37, and 40-43 have been considered but are moot in view of the new ground(s) of rejection, wherein the new ground(s) of rejection relies upon prior art submitted in the IDS filed 10/08/2008.

Conclusion

19. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/08/2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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